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09/782,588	02/12/2001	Robert Kain	A-68950-1/DJB/RMS/DCF	9480

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/782,588

Applicant(s)

KAIN ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 10-12, 18-25 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10-12, 18-25 and 27-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 8 July 2004 and 4 November 2004 in which a Terminal Disclaimer was filed; claims 1 and 18 were amended; and claims 28-33 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 9 April 2004, not reiterated below, are withdrawn in view of the amendments and Terminal Disclaimer. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-4, 6-7, 10-12 and 18-33 are under prosecution.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 6-7, 10-12, 18-25, 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et al (U.S. Patent No. 6,232,066, filed 2 July 1998) in view of Hurd et al (U.S. Patent No. 4,812,216, issued 14 March 1989) or Schembri (U.S. Patent No. 6,261,523, filed 27 April 1999) or Chu (U.S. Patent No. 6,703,247, filed 23 December 1998).

Regarding Claims 1 and 12, Felder et al disclose a method of making a composition and composition comprising substrate comprising a surface having first and second assay

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locations separated by a partition (i.e. physical barrier, Column 5, lines 19-28) wherein the assay location have discrete sites configured to hold a single microsphere (wells or dimples, Column 6, lines 38-51 and Column 8, lines 40-41), said sites separated by a distance of less than 50 $\mu$ m (Column 7, lines 60-62) wherein the substrate comprises a microscope slide (Column 5, line 2). Felder et al teach the composition further comprising a first and second population of microspheres having a bioactive agent randomly positioned on the substrate (Column 8, lines 39-42). Felder et al further teach the composition is covered (e.g. Column 33, lines 49-52) which clearly suggests the composition comprises a lid, but they do not specifically teach a lid. However, lids on assay chambers were well known and routinely used in the art at the time the claimed invention was made as taught by Hurd et al, Schembri and Chu.

As a first example, Hurd teaches a composition comprising substrate having discrete sites of bioactive agents and a lid wherein the lid prevents solution evaporation (Column 6, lines 56-65). Schembri also teach a composition comprising substrate having discrete sites of bioactive agents and a lid wherein the lid prevents solution evaporation (Column 1, lines 66-67 and Column 4, line 66-Column 5, line 19). Furthermore, Chu teaches a composition comprising a substrate having discrete sites of biological agents and a lid wherein the lid prevents contamination within and evaporation from the assay (Column 4, lines 35-65). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known lid of Hurd et al, Schembri and Chu to the composition of Felder et al for the expected benefit of prevents contamination within and evaporation from the assay device as known in the art.

Regarding Claim 2-4, 6-7, 10-12, 19-20 and 23-25, Felder teaches the composition wherein the spacing and separation of the microspheres is 3 $\mu$ m to 5 $\mu$ m thereby encompassing the claimed ranges (Column 7, lines 59-63).

Regarding Claim 21-22, Felder teaches the composition comprises control probes (e.g. second population) wherein they suggest one control probe per well (Column 23, lines 41-67)

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and about 900 per well (Column 6, lines 43-47) thereby providing the claimed ratios of control to test populations.

Regarding Claim 27, Felder et al teach the method wherein the discrete sites are wells "wells-within-wells" (Column 6, lines 43-47).

Regarding Claim 28, Felder et al disclose a method of making a composition and composition comprising substrate comprising a surface having first and second assay locations separated by a partition (i.e. physical barrier, Column 5, lines 19-28) wherein the assay location have discrete sites configured to hold a single microsphere (wells or dimples, Column 6, lines 38-51 and Column 8, lines 40-41). Felder et al further teach the composition is covered (e.g. Column 33, lines 49-52) which clearly suggests the composition comprises a lid, but they do not specifically teach a lid. However, lids on assay chambers were well known and routinely used in the art at the time the claimed invention was made as taught by Hurd et al, Schembri and Chu.

As a first example, Hurd teaches a composition comprising substrate having discrete sites of bioactive agents and a lid wherein the lid prevents solution evaporation (Column 6, lines 56-65). Schembri also teach a composition comprising substrate having discrete sites of bioactive agents and a lid wherein the lid prevents solution evaporation (Column 1, lines 66-67 and Column 4, line 66-Column 5, line 19). Furthermore, Chu teaches a composition comprising a substrate having discrete sites of biological agents and a lid wherein the lid prevents contamination within and evaporation from the assay (Column 4, lines 35-65). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known lid of Hurd et al, Schembri and Chu to the composition of Felder et al for the expected benefit of prevents contamination within and evaporation from the assay device as known in the art.

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Regarding Claim 29, Hurd et al teaches the composition further comprising a sealant i.e. gasket (#210, Fig. 2 and Column 6, lines 62-65, Column 7, lines 42-50). Schembri teaches the composition further comprising a sealant e.g. o-ring (Column 7, lines 64-67).

Regarding Claim 30, Hurd et al teaches the composition further comprising a sealant i.e. gasket (#210, Fig. 2 and Column 6, lines 62-65, Column 7, lines 42-50). Schembri teaches the composition further comprising a gasket i.e. o-ring (Column 7, lines 64-67).

Regarding Claim 31, Hurd et al teaches the composition further comprising a sealant i.e. gasket adapted to fit within an indentation on the substrate or rubber (#210, Fig. 2 and Column 6, lines 62-65, Column 7, lines 42-50).

Regarding Claim 32, Hurd et al teaches the composition further comprising a sealant i.e. gasket adapted to fit within an indentation on the substrate or rubber (#210, Fig. 2 and Column 6, lines 62-65, Column 7, lines 42-50). Schembri teaches the composition wherein the gasket is adapted to fit within an indentation on the substrate (Column 7, lines 59-Column 8, line 3).

Regarding Claim 33, Hurd et al further teach the similar composition comprising a film between the lid and partition (Column 7, lines 42-67) whereby imaging is simpler and more efficient (Column 7, lines 65-67).

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Conclusion**

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Primary Examiner  
Art Unit: 1634  
January 7, 2005